Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE: CELLECT, LLC,

Appellant

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in *Ex Parte* Reexamination Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457

BRIEF OF *AMICI CURIAE* ABBVIE INC. AND INNOVATION ALLIANCE IN SUPPORT OF APPELLANT ON REHEARING

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November 27, 2023

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CERTIFICATE OF INTEREST

Counsel for Amici Curiae certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

AbbVie Inc.

Innovation Alliance

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

AbbVie Inc. — None.

Innovation Alliance — See Attached List of Members.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

None.

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

In Re: Cellect, LLC, No. 22-1292 (Fed. Cir.); and

Cellect, LLC v. Samsung Electronics Co., Ltd., et al., No. 1:19-cv-00438 (D. Colo.).

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None.

November 27, 2023

/s/ Jonathan S. Massey
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Counsel for AbbVie Inc. and Innovation Alliance

Members of Innovation Alliance

- AbbVie Inc.
- Adeia
- Aware, Inc.
- Cantor Fitzgerald, LP
- Digimarc Corporation
- Dolby Laboratories, Inc.
- enviolo
- Immersion
- InterDigital
- Qualcomm, Inc.

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INTEREST OF *AMICI CURIAE*

AbbVie Inc. ("AbbVie"), a global, research-based biopharmaceutical company, has a significant interest in ensuring a fair, predictable, and robust system of patent protection.[1] Since its creation in 2013, AbbVie has invested more than $55 billion in research and development of new medicines. AbbVie's mission is to discover and deliver innovative medicines and products that solve serious health issues today and address the medical challenges of tomorrow.

The Innovation Alliance is a coalition of research and development-based technology companies representing innovators, patent owners, and stakeholders from a diverse range of industries that believe in the critical importance of maintaining a strong patent system that supports innovative enterprises of all sizes. The Innovation Alliance is committed to strengthening the U.S. patent

[1] This brief is filed with the written consent of all parties. No counsel for either party authored this brief in whole or in part, nor did any party or other person or entity other than amici curiae or their counsel make a monetary contribution to the brief's preparation or submission.

system to promote innovation, economic growth, and job creation, and it supports legislation and policies that help to achieve those goals.

INTRODUCTION

The text, structure, and legislative history of 35 U.S.C. § 154(b) speak directly to the question of when and how obviousness-type double patenting ("ODP") should be applied to patent term adjustment ("PTA"). The statute mandates extensions for administrative delay (*i.e.*, PTA) as part of a precise design meant to *guarantee* a minimum 17-year effective patent term. In adopting the PTA provisions, Congress was fully aware of ODP—a judge-made doctrine under which courts may invalidate the later-expiring of two or more non-distinct patents—and prescribed specific instances where ODP would apply to cut short PTA. None of those instances exists here.

The panel's decision adopts an expansive interpretation of the judge-made ODP doctrine that eviscerates Congress' clear statutory choice and thus runs afoul of the separation of powers. Congress sought to guarantee that a patentee would enjoy a minimum 17-year effective patent term, with specific statutory language to address selected situations involving ODP. But the panel has allowed a sweeping use of ODP, a judicially created doctrine, to override the

congressional scheme and improperly cut short PTA for a wide range of patents.

The panel's rationale for its expansive interpretation of ODP lies not in the statutory language nor legislative history but in a series of inferences. It held that, because (a) the statute permits the use of a terminal disclaimer to cut short PTA under certain conditions (*see* § 154(b)(2)(B)), and (b) terminal disclaimers are almost always used to overcome ODP, Congress intended to cut short PTA for *any* patents that are obvious over an earlier-expiring patent. This interpretation ignores the specific statutory language addressing selected situations involving ODP. The fact that Congress considered ODP in enacting the PTA scheme is a reason to honor the choices made by Congress, not to override the balance struck by Congress.

The need for this Court's en banc review is heightened by the divergent approaches taken by different panels of this Court. In *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355 (Fed. Cir. 2018), for example, a different panel held that ODP could not cut short a statutorily assigned patent term, despite similar terminal disclaimer language. *See* 35 U.S.C. § 154(c)(1) ("subject to

any terminal disclaimers"). In *Novartis*, a change in law, the Uruguay Round Agreements Act of 1994 ("URAA"), changed the default patent term from 17-years-from-issue to 20-years-from-filing—causing a post-URAA patent to expire earlier than a pre-URAA patent. In contrast to the panel's approach here, *Novartis* explained that "to require patent holders to truncate any portion of the statutorily-assigned term" would be "inconsistent" with the statutory scheme. *Id.* at 1366. *Novartis* further opined that "[t]o find that obviousness-type double patenting applies here because a post-URAA patent expires earlier would abrogate Novartis's right to enjoy one full patent term on its invention." *Id.* at 1367. *Novartis*, in other words, properly deferred to Congress' handiwork rather than overturning it. The panel's decision here to override the congressional scheme conflicts with the reasoning in *Novartis*.

"[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998). Many patentees have relied on the statutory scheme and early

precedents in deciding to invest billions of dollars in research and driving innovation in the United States. The panel's decision upsets the patent system's bargain and frustrates the reasonable investment-backed expectations of innovators.

This Court should grant rehearing and reverse the judgment of the Patent Trial and Appeal Board or remand.

ARGUMENT

I. The Text, Structure, And Legislative History Of Section 154(b) Speak Directly To When And How ODP Should Be Applied To PTA.

Congress introduced PTA through adoption of the URAA in 1994. In Section 154(b), Congress enacted limited term adjustments for three specific types of administrative delays caused by the USPTO: delays caused by secrecy orders, interference, and appeals that were ultimately successful. *See* 35 U.S.C. § 154(b)(1)-(2) (1994). Section 154(b) also included a detailed scheme prescribing how and under what conditions ODP could limit PTA. Specifically, the 1994 version of the statute contained a narrow exception preventing PTA for patents "subject to a *terminal disclaimer* due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review." *Id.* § 154(b)(2) (emphasis added). This

reference to terminal disclaimers made clear that Congress specifically considered ODP in establishing PTA. As the panel acknowledged, terminal disclaimers and ODP are "inextricably intertwined," because "[t]erminal disclaimers are almost always filed to overcome an ODP rejection." *In re Cellect, LLC*, 81 F.4th 1216, 1228 (Fed. Cir. 2023).

The 1994 exception legislated the use of ODP to cut short PTA caused by USPTO delays associated with "appellate review," but not interference or secrecy orders. 35 U.S.C. § 154(b)(2) (1994). In addition, Congress limited the specific situations under which ODP could cut short PTA—namely, "due to the *issue* of another patent claiming subject matter that is not patentably distinct from that under appellate review." *See id.* (emphasis added). These features of the statute demonstrate that Congress carefully considered the term-cutting effect of ODP and made deliberate decisions about the specific circumstances in which that doctrine should (and should not) apply.

In 1999, Congress revised the PTA provisions to the current language by enacting the Patent Term *Guarantee* Act of 1999. That language expanded the availability of PTA for all USPTO-caused

administrative delays (except for limited circumstances specifically prescribed by statute) in order to "guarantee" a diligent applicant a minimum 17-year effective patent term. Subsection 154(b)(1) is entitled "patent term guarantees," and the subsection uses the term "guarantee" or "guarantees" *four* separate times. A "guarantee," as Congress well knew, is an "assurance"[2] or an "undertaking with respect to (a contract, performance of a legal act, etc.) that it will be duly carried out."[3]

The legislative intent for the revision was clear—to guarantee a minimum 17-year effective patent term, after the earlier URAA had changed the default patent term from 17-years-from-issue to 20-years-from-filing, in an effort to harmonize U.S. patent law with international standards under the General Agreement on Tariffs and Trade ("GATT"). This harmonization had the unintended effect of subtracting from the patent's effective term the time spent during

[2] "Guarantee," MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (10th ed. 1999) *see also* "Guarantee," THE OXFORD MODERN ENGLISH DICTIONARY (2d ed. 1996).

[3] Bryan A. Garner, A DICTIONARY OF MODERN LEGAL USAGE (2d ed. 1995) ("Guarantee").

prosecution at the USPTO. The Patent Term Guarantee Act of 1999 was enacted to ensure that patentees would receive a minimum 17-year effective patent term. A key House sponsor described the PTA provisions as a "core initiative." 145 Cong. Rec. H6944 (1999) (Rep. Rohrabacher); *see also id.* ("This title represents an opportunity to recapture some of the reliance of pre-GATT standards" and "essentially gives back to the nondilatory patent holder . . . a guaranteed 17 year patent term.").

As Senate co-sponsors explained, "the bill will guarantee a minimum 17-year patent term for diligent applicants, addressing concerns that have been expressed since the United States went to a 20-year from filing term of protection with the adoption of the Uruguay Round Agreements Act in 1994." 145 Cong. Rec. S13258 (1999) (Sen. Hatch and Sen. Leahy). The Senate majority leader noted that the bill:

> adds a new provision to compensate applicants fully for USPTO-caused administrative delays, and, for good measure, includes a new provision guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided

> under the pre-GATT standard; in fact, most will receive considerably more.

145 Cong. Rec. S14718 (1999) (Sen. Lott); *see also* H.R. Rep. No. 106-287, 48-49 (1999), 1999 WL 569140 (noting the same).

Congress specifically considered the term-cutting effect of ODP during the 1999 revision and adopted a provision limiting the impact of ODP on PTA. Specifically, Section 154(b)(2)(B) states: "(B) Disclaimed term. No patent the term of which *has been disclaimed* beyond a *specified date* may be adjusted under this section beyond the expiration date specified in the disclaimer." 35 U.S.C. § 154(b)(2)(B) (emphases added). The terms "has been disclaimed" (past tense) and "specified date" show that ODP would be applied only where the applicant has already filed a terminal disclaimer for a particular date. These specific words were chosen as part of a precise design to allow ODP to cut short PTA only in selected situations.

Thus, Congress has repeatedly considered ODP in the context of PTA and set out specific provisions addressing when ODP would cut short PTA. Had Congress intended to extend ODP to additional scenarios, it would have enacted different statutory language. For example, Congress could have revised the 1994 language to say: "A

patent shall not be eligible for extension under this **section** ~~**paragraph**~~ if it ~~**is subject to a terminal disclaimer due to the issue of another patent claiming**~~ **claims** subject matter that is not patentably distinct from **another patent** ~~**that under appellate review**~~." But Congress chose not to do so. A court may not rewrite Congress' statutory language based on its own policy preference. "[E]ven the most formidable policy arguments cannot overcome a clear statutory directive." *BP p.l.c. v. Mayor & City Council of Baltimore*, 141 S. Ct. 1532, 1542 (2021) (quotations and citation omitted).

II. The Panel's Expansive Interpretation Of ODP Runs Afoul Of The Separation Of Powers.

The panel decided that the judge-made choices regarding ODP should take precedence over Congress' judgment that all patent applications facing administrative USPTO delay be granted a term adjustment, except in limited circumstances specifically prescribed by statute. The panel's decision therefore runs afoul of the separation of powers.

The panel's decision assumes the very "'legislation-overriding' role" that the Supreme Court condemned in *SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC*, 580 U.S. 328, 335 (2017)

(citation omitted). Where Congress "speaks directly" to an area of law, *id.* at 334, a court-made doctrine cannot serve to "subtract" or "add" to what has already been legislatively prescribed. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 612, 616 (2023) ("Congress has included [a mandate] . . . designed to achieve the balance it wishes. Our only duty in this case lies in applying that mandate faithfully.").

In *SCA Hygiene*, the Supreme Court vacated a judgment of this circuit for applying laches, a defense created by courts of equity, to limit the six-year statute of limitations allowed under § 286 of the Patent Act. *See* 580 U.S. at 346. The Court found that, by enacting a statute of limitations, Congress "sp[oke] directly" to the timeliness of a patent claim. *Id.* at 334. The Court warned that allowing a judge-made doctrine to bar a patent claim brought within the congressionally authorized limitations period "would give judges a 'legislation-overriding' role that exceeds the Judiciary's power." *Id.* at 335 (quoting *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. 663, 680 (2014)).

The same reasoning applies here. Congress has directly spoken to how ODP should apply to PTA, and that is the end of the matter.

When Congress "'speak[s] directly to [the] question' at issue," judge-made law created by federal courts is automatically displaced, even absent the kind clear congressional statement required to preempt state law. *American Elec. Power, Co. v. Connecticut*, 564 U.S. 410, 424 (2011) (citation omitted; brackets in original). Under "the separation of powers," federal judge-made law disappears "when Congress addresses a question" by adopting a statute that "governs" the issue. *City of Milwaukee v. Illinois*, 451 U.S. 304, 314-16 (1981). In the case of federal judge-made law, courts "start with the assumption that it is for Congress, not federal courts, to articulate the appropriate standards to be applied as a matter of federal law." *Id.* at 317 (internal quotation marks omitted).

The panel's decision fails to adhere to the proper judicial role under the separation of powers.

III. The Panel's Per Se Rule Is Based On Flawed Reasoning.

In adopting its per se rule, the panel first pointed to Section 154(b)(2)(B), which limits PTA from extending beyond a date specified in the applicant's terminal disclaimer. Next, the panel relied on the fact that terminal disclaimers are almost always used to overcome

ODP to conclude that Congress intended to *prevent* the use of PTA by *any* patent that is obvious over an earlier expiring patent. *See Cellect*, 81 F.4th at 1227-28.

The panel's reference to the terminal-disclaimer provision in Section 154(b)(2)(B) proved the opposite of what the panel opined. The reference shows that Congress contemplated ODP and prescribed a specific statutory regime for addressing it. A court must follow that prescription and is not free to alter the balance. The statute mandates that ODP may cut short PTA only for those patents whose term "*has been* disclaimed beyond a *specified date*." *See* § 154(b)(2)(B) (emphases added).

Further, the panel opined that the statute offers redemption for affected patents so long as they include terminal disclaimers. *See Cellect*, 81 F.4th at 1231. The panel suggested that, if patent applicants preemptively include terminal disclaimers, they could still take advantage of PTA for their patents to the extent the adjustments do not extend the patent term beyond the disclaimer. But there is no language in the statute supporting the inference that Congress intended for Section 154(b)(2)(B) to be used as such a convoluted

solution to the court's application of ODP. The proposed solution is not Congress-made; it is a court-made "solution" for the morass that results from the application of a court-made doctrine to an already complete statutory scheme. The panel's reliance on the potential for terminal disclaimers is therefore inappropriate. *See City of Milwaukee*, 451 U.S. at 323 (policy disagreement by court "is no basis for the creation of federal common law").[4]

CONCLUSION

The petition for rehearing should be granted.

[4] The question of whether the patents at issue are barred by ODP under a proper construction of the relevant text and history of Section 154(b) has neither been examined by the USPTO nor litigated before the Federal Circuit panel, and amici curiae also take no position on whether the USPTO should implement rules in this regard.

Dated: November 27, 2023

Respectfully submitted.

By: *<u>/s/ Jonathan S. Massey</u>*

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PROOF OF SERVICE

I hereby certify that on November 27, 2023, I electronically transmitted this Brief *Amici Curiae* to the Clerk of the Court using the Court's ECF system. I further certify that all counsel of record are being served with a copy of this Brief via the Court's ECF system.

/s/ Jonathan S. Massey
Jonathan S. Massey

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 35(g)(3). The brief contains 2585 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft 365 MSO (Version 2310) in 14-point Century Schoolbook font.

Dated: November 27, 2023

/s/ Jonathan S. Massey
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